

Information Disclosure Statements

Although Applicants believe the Examiner intended to indicate his consideration of the references listed on page 3 of 5 of the Form PTO-1449 mailed to Patent Office on October 20, 1999 (Tab A), Applicants respectfully request clarification by returning a copy of the Form PTO-1449 with all of the boxes corresponding to all of the references on page 3 of 5 initialled. Additionally, Applicants respectfully request that the Examiner return a copy of the Form PTO-1449 mailed to the Patent Office on January 24, 2000 (Tab B), with all of the boxes corresponding to all of the references listed on the form initialed. A copy of each of the Form PTO-1449s is enclosed, for the Examiner's convenience.

Because these documents were earlier filed in a timely manner, Applicants respectfully submit that no fee is due for their consideration. However, in the event a fee is due for their consideration, authorization is given for charging deposit account 20-0531 for that fee. If other action is required for these references to be considered, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

Rejection under 35 U.S.C. § 103(a)

Claims 19-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson. Independent claim 19 recites, in part, a seal comprising a bladder filled with a molded material having a durometer value less than about ten on a Shore OOO scale.

Briefly, Johnson discloses a diver's face mask having a rigid transparent frontal portion and rigid transparent peripheral portions. See Johnson, col. 1, lines 51-52. The mask includes sealing means (20), which is designed to accommodate differing facial features by including a suitably shaped layer of pliable neoprene (21) wrapped around and bonded onto a length of resilient surgical rubber tubing (22). See Johnson, col. 2, lines 42-45 and Figure 2A (emphasis added).

As a preliminary matter, Applicants respectfully submit that Applicants teach the benefits of the seal recited in claim 19. On page 3, lines 19-21, the application specification highlights a need to overcome the limitations of known designs by providing an improved nasal mask which provides a consistent, reliable nasal area seal, while being comfortable to wear. Compliance with a treatment regimen for a respiratory ailment may be problematic for a patient if the

discomfort of wearing the mask exceeds the discomfort associated with the respiratory condition. See Specification, page 2, lines 1-6. Accordingly, masks according to the of present invention allow for comfortable delivery of a breathable gas to a user. See Specification, page 3, line 1. Both the softness of a gel seal according to the invention and the design of devices according to the invention which invite minimal contact between the user's epidermal areas and the device, combine to create this comfortable and reliable seal about the user's nares. See Specification, page 3, lines 5-8. See also, Specification, page 7, lines 15-21. Furthermore, care is taken to describe a manner in which one can determine the durometer of the seal fill material, because this material is too soft for measurement by ASTM-approved Shore durometer test methods. See Specification, page 14, lines 13 to page 15, line 27. As well, the film disposed against the user's skin is maintained relatively thin, so as not to stiffen the seal. See Specification, page 16, lines 13-14.

Applicants respectfully submit that Johnson teaches away from Applicants' recited invention and that neither Johnson nor the knowledge of one of ordinary skill in the art suggest a modification of Johnson's suitably shaped layer of pliable neoprene (21) wrapped around and bonded onto a length of resilient surgical rubber tubing (22) to obtain the seal recited in claim 19.

Specifically, Johnson teaches away from the invention recited in claim 19 as follows. Johnson discloses that, "[i]n recognition for the fact that the mask is subjected to fluctuating ambient pressures as a diver changes his depth, pressure compensation holes 22a ... provide fluid communication between the interior of the rubber tube 22 and the mask interior." Johnson, col. 3, lines 24-29 and Fig. 2A. As such, Johnson states that "[a]s the diver goes deeper, ... a small portion of the air is passed to the interior of tube 22 via the holes. Were the holes omitted, that is, if tube 22 is sealed to define a dead air space, this air space would collapse under increasing ambient pressure and the mask would lose its seal." Johnson, at lines 29-37. Clearly, this disclosure teaches one of ordinary skill in the art away from filling Johnson's hollow seal with a molded material, because doing so would eliminate fluid communication between the interior of the rubber tube and the mask interior, possibly compromising the integrity of the seal. Thus, Johnson actually discourages a bladder filled with a molded material because it underscores the importance of a hollow tube being in fluid communication with the mask

interior. As such, Johnson is not properly modifiable or combinable with any other reference. See MPEP, § 2145(X)(D)(2); see also MPEP § 2141.02 and § 2143.01.

Moreover, Applicants respectfully submit that there is no motivation to modify Johnson in order to arrive at the invention recited in claim 19. It is well settled that, to modify a reference, there must be some suggestion or motivation to do so in the reference itself or in the knowledge generally available to one of ordinary skill in the art that lies outside the disclosure of the patent application. See, e.g., MPEP §2142 (8th Ed., August 2001). Absent this motivation, a rejection under 35 U.S.C. § 103(a) should not be maintained.

Neither Johnson nor the knowledge of one of ordinary skill in the art provides the requisite suggestion or motivation to modify Johnson's hollow rubber tube wrapped in neoprene to arrive at the invention recited in claim 19. In particular, Johnson discloses a face mask that is configured to accommodate differing facial contours among divers and has a seal incorporating pressure compensation to ensure sealing of the mask interior. Applicants respectfully submit that teachings of Johnson are incompatible with a bladder filled with a molded material in a predetermined configuration. For example, Johnson's neoprene layer is approximately one eighth of an inch thick, which, along with the interior rubber tubing, requires some degree of tightening of a resilient strap about the diver's head to elastically deform the neoprene layer and the rubber tubing to create a seal. Because the Johnson mask is used for underwater activities, where the integrity of the seal is extremely important, the user's tolerance for discomfort is relatively high. In addition, as discussed above, Johnson actually discourages a bladder filled with a molded material because it underscores the importance of a hollow tube being in fluid communication with the mask interior for pressure compensation.

In contrast, Applicants' masks and associated seals allow for comfortable delivery of a breathable gas to a user. Both the softness of a gel seal according to the invention and the design of devices according to the invention which invite minimal contact between the user's epidermal areas and the device, combine to create a comfortable and reliable seal about the user's nares. Applicants disclose that the outer layer of the seal should be thin to avoid stiffening of the seal. Moreover, as recited in claim 19, Applicants' seal is configured to seal against external skin proximate at least one naris at a base of a nose of a user. This delicate area of the user's face requires minimal contact and pressure to avoid irritation and patient discomfort. Thus, Johnson

fails to motivate one of ordinary skill in the art to modify the Johnson seal to obtain the seal recited in claim 19.

Additionally, it appears that the knowledge of one skilled in the art would not motivate modifying Johnson to obtain the seal recited in claim 19. In fact, International Patent Application Publication Serial Number WO 97/09090 ("Barnett"), cited by the Examiner in the previous Office Action dated January 4, 2002, discourages a skilled artisan from using as a seal material a very soft gel material with a durometer value below that of a human fat tissue. As such, the skilled artisan would not be motivated to modify Johnson to include a material having a durometer value less than about ten on the Shore 000 scale. More specifically, Barnett discloses that the facial seal 18 has a resiliency, as defined by durometer measured on the Shore 00 scale, of about 10 or softer and, most preferably, about 0. See Barnett, page 10, lines 2-6. Barnett reports that such resiliency corresponds substantially to that of human fat tissue. See Barnett, page 10, lines 6-9. It is emphasized, however, that the facial seal must exhibit some measurable recoil memory. See Barnett, page 10, lines 33-34. Barnett teaches that to achieve recoil memory and other properties, the annular member is formed from a gel substance that, while purportedly virtually indistinguishable from human fat tissue when measured on Shore 00 scale, exhibits a resiliency or durometer on the Shore 000 scale of from about 20 to about 45. See Barnett, page 11, lines 5-13. Barnett specifically contrasts the substance with human fat tissue, which registers a durometer of about 10 on the Shore 000 scale. See Barnett, page 11, lines 13-15. More specifically, Barnett states, at page 10, lines 21-33:

[A]ny respiratory mask facial seal possessing structural characteristics essentially identical to fat would be impractical from a usage standpoint. That is, if a facial seal were fabricated from a material structurally indistinguishable from human fat tissue in terms of resiliency, it may tend to sag into an amorphous shape under the influence of gravity and thus would not effectively conform to the contours of a user's face even if headstrap tension was quite high. It will be appreciated, therefore, that a properly designed facial seal must substantially but not identically mimic human fat tissue from a structural, particularly resiliency, perspective.

Barnett, thus, teaches a skilled artisan not to use soft material of less than about 20 on the Shore 000 scale, and, thus, provides no motivation to use a soft material having a durometer value of less than about ten on a Shore 000 scale, because it "would be impractical...."

In view of the remarks set forth above, Applicants respectfully submit that independent claim 19 is novel and non-obvious over Johnson. Accordingly, reconsideration and withdrawal of the rejection of pending claim 19 under 35 U.S.C. § 103(a) as unpatentable over Johnson is respectfully requested. Consequently, Applicants further request reconsideration and withdrawal of the rejection of pending claims 20-29 under 35 U.S.C. § 103(a) because each depends from allowable base claim 19.

Applicants respectfully submit that, in light of the foregoing Response, the claims are in condition for allowance and request the application proceed to issue. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,



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